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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,662	01/11/2002	Andreas Jordan	1214.00026	9966

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/914,662	JORDAN, ANDREAS	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-3,6,7 and 9-16 is/are pending in the application.

4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1, 3, 6, 7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 6, 7 and 9-16 are pending. Claims 9-16 remain withdrawn from consideration. Claims 1-3, 6 and 7 are under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-3, 6 and 7 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 1 requires that the method of claim 1 be carrier out with the culture medium as set. forth previously in claim 8. Claim 1 encompasses all types of cancer cells residing in solid tissues which can be separated by mechanical fragmentation. This includes all adenocarcinomas, carcinomas, sarcomas, melanomas and gliomas and other nervous system tissues. It is noted that culture conditions for each tumor cell type requires optimization. Each ingredient in claim 1 is specified as a range of weight per volume amounts. Claim 1 requires 7 inorganic salts, 21 amino acids, 19 vitamins and 6 other ingredients, all of which require optimization to a value within the specified range. It is noted that out of the "classic media" formulations, such as RPMI, MEM,

DMEM, F-12K, DMEM-F12, L-15, McCoy's 5A, Iscove's Modified Dulbecco's and Hybri-Care, only RPMI requires Ca(No3)2, and none require both Ca(NO3)2 and CaCl2. Primary tumors are a mixture of tumor cells, corresponding normal cells, stromal cells and immune cells (Freshney, Culture of Animal Cells, 1994, page 350-351, see page 351, first paragraph under "Characterization"). The art teaches that tumor cells taken from patients, in addition to requiring the optimization of culture conditions to support the selected cell type, require conditions to prevent the "overgrowth" of connective tissues and vascular cells which predominate conventional culture systems (ibid, see page 350, bridging paragraph between columns 1 and 2). The art teaches the necessity of providing selective conditions which replace any of the growth factors provided by the stoma in vivo (ibid, see page 351, especially column 1, last two sentences). It would be undue experimentation to one of skill in the art to practice the invention of claim 1 with the recited medium composition for every type of cancerous tissue encompassed by claim 1 because each of the ingredients of claim 1 require optimization to support each tumor type and suppress the overgrowth of contaminating connective tissues and vascular cells, and none of the ingredients are specified without a range. Claim 1 reads on tumor biopsy specimens taken from patients. Thus, one of skill in the art would be restricted in the type of material used for the optimization, because it is well know that tumor cell lines have different requirements for viability than tumor explants or biopsy samples. Thus, one of skill in the art would not have unlimited amounts of tissue to commit to optimization studies. Given the breath of both of claims 1 and 8, and the lack of specific teachings in the specification which would serve to direct one of skill in the art to particular set values of the different ingredients of claim 1 to a particular tumor type, such as breast adenocarcinoma or melanoma, one of skill in the art would be subject to undue experimentation in order to carry out the instant methods requiring the broadly claimed medium

Applicant argues that the counter ions present in the instant formulation make no difference to the end product, stating that when in solution the culture medium does not have Ca(NO3)2 and Na2SO4 existing separately but as dissociated ionic components, and therefore it does not make a difference if one of skill in the art chooses Na(NO3)2 and CaSO4 versus Na2SO4 and Ca(NO3)2. This has been considered but not found persuasive. The ingredients listed in claim 1 are not listed as alternative ingredients but as a collective formula. It is further

notes that the ranges for all the ingredients do not encompass zero for any ingredient. Further, the same argument applied to the above rejection for the need to optimize for every tumor type with regard to the medium formulation can be applied to the counter ions in solution as well as the ingredients used to formulate the solution, because one of skill in the art would be subjected to undue experimentation in order to make the medium useful for the propagation of primary tumor cells taken from patients.

Applicant argues that the medium need only to be optimized for a tumor type in order to grow a tumor taken from a patient, which is well within the grasp of those skilled in the art at culturing tumor cells. this has been considered but not found persuasive. The art teaches that tumor cells taken from patients, in addition to requiring the optimization of culture conditions to support the selected cell type, require conditions to prevent the "overgrowth" of connective tissues and vascular cells which predominate conventional culture systems (ibid, see page 350, bridging paragraph between columns 1 and 2). Thus optimization of conditions to support the selected type of tumor cell has no bearing on the optimization of conditions to prevent overgrowth from explants.

Applicant argues that the difference in counter ions have no bearing on the ultimate composition of the culture medium. this has been considered but not found persuasive. Freshney teaches that Calcium ions and chloride ions regulate membrane potential, and other salts contribute to the osmolality of the medium (page 88, second column first full paragraph). In the instant invention, the ratio of Calcium to chloride will be altered because Calcium nitrate is required. Based on the teachings of Freshney it is reasonable to conclude that a decrease in chloride will have an effect on cellular membranes, and therefore the effects of the counter ions cannot be discounted.

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella, Ph.D./
5/28/2007